Radiofrequency Ablation Effective in Barrett's

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CHICAGO — Radiofrequency ablation appears to provide a durable, safe, and complete eradication of dysplastic Barrett's esophagus in most patients.

Two years after undergoing radiofrequency ablation (RFA), 96% of patients with complete eradication of intestinal dysplasia at 1 year were still free of abnormal cells, Dr. Nicholas J. Shaheen said at the annual Digestive Disease Week.

Only 2 of the 50 patients analyzed experienced disease recurrence; both had relatively long lengths of high-grade dysplasia at baseline, which recurred as short lengths of low-grade dysplasia 2 years later, said Dr. Shaheen of the University of North Carolina at Chapel Hill.

Dr. Shaheen presented 2-year follow-up data from the Ablation of Intestinal Metaplasia Containing Dysplasia (AIM Dysplasia) trial. The study randomized 127 patients with dysplastic Barrett's esophagus in a 2:1 ratio to RFA or a sham procedure. Previously, 1-year data showed that the procedure completely eradicated dysplasia in 81% of those with high-grade dysplasia and in 90% of those with low-grade dysplasia. Overall, 77% of the ablation group had complete eradication (N. Engl. J. Med. 2009;360:2277-88).

Regardless of dysplasia level, the 84 patients who received ablation were significantly more likely than the 43 in the control group to have complete eradication of dysplasia, Dr. Shaheen reported.

The sham procedure was associated with eradication of intestinal dysplasia in 23% of patients who had low-grade dysplasia and 19% of those who had high-grade dysplasia. The patients in the control group were much more likely to show disease progression at 1 year (16%) than were the patients in the ablation group (4%), he said.

Among patients with low-grade dysplasia, 98% of the biopsy samples in the ablation group were free of intestinal metaplasia at 1 year, compared with 57% of biopsies in the control group. Similarly, among patients with high-grade dysplasia, 98% of the specimens from patients who underwent ablation were free of intestinal metaplasia at 1 year, compared with 59% of samples from control patients.

Patients who received the sham procedure were offered ablation after the first year of follow-up; all accepted. Currently, 119 patients have been treated.

The follow-up study reported at the meeting included 50 patients with complete eradication of dysplasia at 1 year and 2 full years of follow-up data. Low-grade dysplasia was present at baseline in 32 patients, high-grade in 18 patients. The mean age at baseline was 65 years; the mean length of Barrett's esophagus at baseline was 4 cm.

At 2 years, 96% of patients with a complete response to RFA at 1 year were still free of abnormal cells.

DR. SHAHEEN

The procedure was considered very safe, Dr. Shaheen said. Of the four serious adverse events, three occurred in the first year (two cases of chest pain requiring admission; one gastrointestinal hemorrhage in a patient on antiplatelet therapy). During the second year, one more patient required admission for evaluation of chest pain.

Esophageal stricture developed in five patients during the first year and in four others during the second year. Six of the strictures developed after circumferential ablation and three after focal ablation. "Of note, three of these patients had a stricture prior to the procedure," he said. All strictures were easily resolved with a median of 1.5 dilations.

In the overall intent-to-treat analysis, 92% of patients who had complete response at 1 year maintained complete response at 2 years. The rate was higher, at 96%, in the per-protocol analysis.

Among patients with high-grade dysplasia at baseline, 83% retained complete response (complete eradication of intestinal metaplasia) at 2 years in the intent-to-treat analysis; 88% did so in the per-protocol analysis. Among patients with low-grade dysplasia at baseline, 97% retained complete response in the intent-to-treat analysis, and 100% in the per-protocol analysis.

Only two patients showed disease progression, Dr. Shaheen reported. "One patient had a 6-cm length of high-grade dysplasia at baseline, and a 1-cm section of low-grade dysplasia at 2 years. The other had a 5-cm section of high-grade dysplasia at baseline, and a 0.5-cm length of low-grade dysplasia at the follow-up."

Dr. Shaheen disclosed that he has received research grants from BÂRRX Medical, which sponsored the study and manufactures the endoscopic ablation system used in it. He has also received research funding and honoraria from numerous pharmaceutical companies. ■

Mary Ann Moon contributed to this report.

Occasional Drinking May Boost Liver Cancer Risk in NASH Patients

CHICAGO — Drinking even two or fewer alcoholic drinks per day nearly quadruples the risk of hepatocellular carcinoma in patients with cirrhosis due to both nonalcoholic steatohepatitis and hepatitis C infection, a prospective study has concluded.

The study is the first to confirm such a link in patients with nonalcoholic steatohepatitis (NASH), and emphasizes the need for proactive counseling among these patients, Dr. Nizar Zein said at the annual Digestive Disease Week.

'Physicians following these patients should counsel complete abstention from alcohol.'

DR. ZEIN

"Physicians following these patients should counsel complete abstention from alcohol," Dr. Zein said in an interview. "If we can get them to do that, we may in the future be able to lower the burden of cancer associated with this disease."

About 20% of patients with NASH will develop cirrhosis, a proven risk factor for hepatocellular carcinoma (HCC), said Dr. Zein, chief of hepatology and medical director of liver transplants at the Cleveland Clinic. "Despite this link, there is a lack of large population studies regarding the risk of HCC in patients with cirrhosis due to NASH."

In a retrospective analysis, he and his colleagues studied 510 patients with cirrhosis not related to alcohol intake, who were treated at the clinic from 2003 to 2007. Cirrhosis was due to NASH in 195 patients, and to hepatitis C viral infection in 315. Patients with NASH were older than those with hepatitis C (57 vs. 45 years) and had a higher body mass index (35 vs. 28 kg/m^2). The mean score on the Model for End-Stage Liver Disease (MELD) scale was 11 in the NASH group and 12 in the hepatitis group—not a significant difference.

Over the 3-year follow-up period, 18% of the entire study population developed HCC. The rate was significantly higher in the hepatitis group than in the NASH group (20% vs. 13%).

A multivariate analysis examined risk factors associated with the development of HCC in those patients with NASH. Not surprisingly, older age at cirrhosis diagnosis was significantly associated with developing cancer, increasing the risk by 7%.

Even patients who drank only small amounts (fewer than two drinks per day) were almost four times more likely to develop HCC than were nondrinkers (hazard ratio 3.6). Heavy drinking (more than two drinks per day) increased HCC risk to the same extent as social drinking. Body mass index, smoking, diabetes, and MELD score were not significantly related to HCC in patients with NASH.

"This study shows for the first time that patients with NASH are at high risk for HCC, especially if they drink, and, as such, would probably benefit from a regular screening strategy," Dr. Zein said.

No studies have addressed the optimum screening method. However, Dr. Zein said, a reasonable option might be ultrasound examination every 6 months. ■

Mass Screening via Flexible Sigmoidoscopy Scrutinized

CHICAGO — The first randomized controlled trial to investigate the impact of population-based flexible sigmoidoscopy screening failed to find any significant reductions overall in colorectal cancer incidence or mortality.

But the Norwegian Colorectal Cancer Prevention trial did find that individuals who actually underwent screening were 60% less likely to die from colorectal cancer than were controls who were not screened—a significant reduction.

Dr. Geir Hoff of the Cancer Registry of Norway in Oslo presented 7-year data at the annual Digestive Disease Week. The study took place in Oslo and in Telemark County, Norway. It randomized 55,736 adults aged 55-64 years to an invitation for one-time flexible sigmoidoscopy (13,823) or to no invitation (41,913). Almost 64% of those invited (8,846) did get screened. At screening, 19% had a neoplastic lesion and 5% had a high-risk adenoma or invasive cancer (BMJ 2009;338:b1846).

In the intent-to-screen analysis, cancer risk did not differ between the screening and control groups (135 vs. 132 cases/100,000 person-years). Nor was there a significant difference in the incidence of rectosigmoidal cancers (58 vs. 79 cases/100,000 person-years).

During the follow-up period, 24 participants in the screening group and 99 in the control group died from colorectal cancer. Compared with the control group, total colorectal cancer death was decreased by 27% and rectosigmoidal cancer death by 37% in the screening group—neither was a significant reduction.

The numbers were better for those who actually attended the screening. Total colorectal cancer death was 59% lower in the screened group than in the control group, and rectosigmoidal cancer death was 76% lower—both were significant differences.

The 7-year follow-up period may not have been long enough to allow colon cancers to develop and cause death, Dr. Hoff said. ■